Serial No. 09/273,646

REMARKS

Claims 69-72 and 74-86 are in the case and presented for reconsideration. Claim 73 has been canceled. Claims 69, 74 and 83 have been amended. No new matter has been added.

The undersigned has been authorized to prosecute the above-identified application in the form of an Associate Power of Attorney which is enclosed herewith. Accordingly, please direct any telephone inquiries to the undersigned at (732) 524-2218. Additionally, please note that future correspondence in association with the above-identified application should be sent to the new address listed on the Associate Power of Attorney.

Claims 69-81, 83-86 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 4,821,731 (Martinelli et al.). With respect to this rejection, the Examiner has stated:

> The claims are directly readable on Martinelli et al. which disclose all of the claimed structural elements including a catheter 20 having a distal portion 24 for applying laser energy for ablation, an ECG monitor, and position sensing means for sensing the position of the catheter distal end (see columns 7-10).

Claim 82 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Martinelli et al. in view of U.S. Patent 5,588,432 (Crowley). With respect to this rejection, the Examiner has stated:

> Martinelli et al. disclose a medical diagnostic and treatment system. Martinelli et al disclose all of the claimed invention except for a means for rotating or deflecting the distal end of the catheter. Crowley discloses a catheter for image and ablation in the heart that includes a means for steering the catheter to the desired location within the body. It is a well known in the art that positioning a catheter within the heart of a patient requires controlling the catheter by bending or rotating the tip of the catheter. Therefore, it would have been obvious to one skilled in the art to have modified Martinelli et al. such that it includes a means for steering the catheter within the body in order to ensure safe and accurate positioning of the catheter as is well known in the art and taught by Crowley.

With respect to these rejections, the Applicant would like to outline particular aspects of these cited prior art references. Martinelli et al. discloses an acoustic image system and method using an electro-acoustical transducer means 34 secured to a tip section 30 of a catheter 20 in order to transmit a beam of acoustical pulses from the tip section 30. Column 6, lines 29-46.

The position of the transducer means 34 on the catheter 20 is determined by means for generating reference signals including means in the form of transducer 60 for generating an ultrasonic reference signal at a pre-selected frequency in order to determine the position of the transducer means 34. Column 7, lines 36-42. The means for generating the reference signals also includes an electromagnetic radiation illuminator 70 for transmitting a pair of reference fields in a direction of distal end 24 of the catheter 20 which is used for determining angular orientation wherein the illuminator 70 includes a pair of coils 72a and 72b. Column 7, lines 56-67. Additionally, a relatively small antenna, in the form of a single loop 100, is positioned on the distal end 24 of the catheter 20. Column 8, lines 1-12. It is important to note that location (position) information can only be determined by the ultrasonic transducer means 34 and the ultrasonic reference signal transducer 60; and that radiation illuminator 70 and single loop 100 are only capable of determining angular orientation. Moreover, Martinelli et al. does not teach or suggest the ability to obtain position and orientation coordinate information.

Crowley et al. is specifically directed toward an acoustic imaging system for use within the heart which utilizes a catheter for providing high resolution ultrasonic images. Although several embodiments for the catheter of this acoustic imaging system are described, it is clear that in every instance, the position of the catheter is determined based solely on high resolution ultrasonic images of anatomical structures surrounding the catheter. Column 3, lines 32-37.

For example, Crowley et al. describes a micro-acoustic imaging catheter 6 having an ultrasonic transducer 10 driven by a special, high fidelity flexible drive shaft 18. Column 14, line 61 - Column 15, line 4. The drive shaft 18 is an assembly formed of a pair of closely wound coils 26 and 28 wound in opposite helical directions. Column 15, lines 27-31. The ultrasonic transducer 10 includes an acoustic lens 52 capable of scanning a conical surface. Column 16, lines 2-11. The transducer 10 is connected to a tubular sleeve 29 which is telescopically connected to the drive shaft 18 (inner coil 28). Column 16, lines 12-15.

With respect to the Crowley et al. catheter, it is important to note that position information for the catheter 6 is not obtained from the transducer 10, but rather, is obtained only from the drive shaft 18 which is actually located at the proximal end of the catheter 6. This particular manner for obtaining position information for an acoustic imaging system is clearly supported in Crowley et al. where it is stated:

> Because position information is not measured at the distal tip of the catheter, but rather from the drive shaft at the proximal end, only with a torsionally stiff and true drive shaft can accurate position information and display be obtained. Column 17, lines 49-53.

Moreover, as specifically addressed in Crowley et al., this position information is obtained based solely on the high resolution ultrasonic images, i.e., the position of the catheter relative to the taken images of the cardiac anatomy (various heart chambers, valves, annuleses, etc.). Column 3, lines 32-37. Furthermore, in Crowley et al., there is no mention or inference that the position information obtained relates to position coordinates and/or orientation coordinates. Additionally, in Crowley et al., there is absolutely no mention or inference that the ablation device is an active portion capable of applying laser energy in order ablate a portion of a heart.

Turning now to the present invention, Claims 69, 74 and 83 have been amended in order to more particularly point out and distinctly claim the present invention. Claim 69 (Amended) is directed toward a system for percutaneous treatment of a patient's heart comprising a catheter wherein the catheter has a proximal end and a distal end; an active portion at the distal end of the catheter for applying laser energy operable to ablate a portion of the heart; and a position sensor responsive to magnetic fields for generating signals for determining position and orientation coordinates of the catheter distal end.

Additionally, Claim 83 (Amended) is directed toward a method of treating a patient's heart comprising the steps of (a) percutaneously inserting a catheter into a heart of a patient wherein the catheter has a proximal end and a distal end and an active portion at the distal end of the catheter for applying laser energy and a position sensor responsive to magnetic fields for generating signals; (b) sensing the position of the catheter distal end using magnetic fields and

the signals generated by the position sensor by determining position and orientation coordinates of the catheter distal end; (c) using the position sensor to reference the catheter distal end based on the position and orientation coordinates; (d) positioning the catheter such that its distal end is adjacent to tissue of the heart to be treated based on the position and orientation coordinates; and (e) applying laser energy from the active portion to the patient's heart tissue.

The support for the amendments outlined above can be found in the Applicant's Specification, for example, page 6, lines 8-35 and page 17, line 32--page 18, line 3.

Accordingly, neither Martinelli et al. nor Crowley, either alone or in combination with each other, describe, suggest or infer the claimed present invention of Claim 69 (Amended) and the dependent claims therefrom, either directly or indirectly (Claims 70-72 and 74-82) and Claim 83 (Amended) and dependent Claims 84-86 which depend either directly or indirectly therefrom. Therefore, the claimed present invention is believed to be both patentably distinct and non-obvious over the cited prior art references and favorable action is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made".

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 69. (Amended) A system for percutaneous treatment of a patient's heart, comprising:

a catheter, the catheter having a proximal end and a distal end;

an active portion at the distal end of the catheter for applying laser energy operable to ablate a portion of the heart; and

a position sensor [operable to provide sensing of the] responsive to magnetic fields for generating signals for determining position and orientation coordinates of the catheter distal end.

Claim 74. (Amended) The system for percutaneous treatment of Claim [73] 69, wherein the position sensor includes at least two non-coplanar magnetic elements.

Claim 83. (Amended) A method of treating a patient's heart comprising the steps of:

(a) percutaneously inserting a catheter into a heart of a patient, the catheter having a proximal end and a distal end, an active portion at the distal end of the catheter for applying laser energy, and a position sensor responsive to magnetic fields for generating signals;
(b) sensing the position of the catheter distal end using magnetic fields and the signals generated by the position sensor by determining position and orientation coordinates of the catheter distal end;
(c) using the position sensor to reference the catheter distal end based on the position and orientation coordinates;
(d) positioning the catheter such that its distal end is adjacent tissue of the heart to be treated based on the position and orientation coordinates; and
(e) applying laser energy from the active portion to the patient's heart tissue.